UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Kable Davis, MS, PM 03

From: Eric Bohnenblust, Ph.D., Entomologist

Secondary Review: Jennifer Saunders, Ph.D., Senior Biologist

Date: 2/22/2017

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

THIS DER DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 383815, 405087
Decision no.: Reregistration
Submission no: Reregistration
Action code: Reregistration
Product Name: No Fly Zone
EPA Reg. No or File Symbol: 83588-1
Formulation Type: Permethrin Treated Fabric
Ingredients statement from the label with PC codes included:
Permethrin 0.52% PC: 109701
Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m^2 or mg/cm^2 or mg/kg body weight as appropriate): 0.52% equates to 0.125 mg permethrin/cm^2
Use Patterns: Permethrin treated fabric for consumer and military clothing, gear, and dog and horse products/gear

I. Action Requested: Review three studies submitted under Reregistration to support repellent efficacy of permethrin treated fabrics against mosquitoes, ants, ticks, chiggers, flies, and midges.

II. Background: The registrant submitted three studies testing efficacy of the registered product against mosquitoes. None of the three studies tested efficacy of the treated fabric against ants, ticks, chiggers, flies, or midges. MRID 47871301 was previously reviewed for DP 371727; the conclusions from the previous review are presented below. For detailed methods and results from MRID 47871301 please see the previous review.

III. MRID Summary:

47871301. AMENDED FINAL REPORT: Bioassay for insecticidal activity of treated fabric samples against adult mosquitoes.

(1) **Conclusion: Unacceptable.** This study does not support any efficacy claims for EPA Reg. No. 83588-1. Laboratory bioassays are not adequate to support claims of “repels” for treated fabrics. In addition, 15-30 minute

exposures were required to achieve consistent knockdown of 75% or above and these exposure intervals are too long. The number of mosquitoes in the control treatments was also not adequate. For testing the efficacy of treated clothing for repelling and preventing bites from mosquitoes, studies should test efficacy using human subjects wearing treated fabric.

47853601. Bioassay for Insecticidal Activity of Treated Fabric Samples Against Mosquitoes.

(1) non-GLP

(2) **Methods and Results:** This study is an earlier, incomplete version of MRID 47871301, and the results were reviewed under MRID 47871301 above.

(3) **Conclusion: Unacceptable.** Please see MRID 47871301 above for conclusions regarding these data.

48256101. The Efficacy of NoFly Zone.

(1) non-GLP

(2) **Methods:** This study evaluated the protection from mosquito bites provided by permethrin treated military uniforms (product specific binding method, NoFlyZone fabric 50% cotton/50% nylon) on four human subjects. Treatments included untreated fabric, unwashed permethrin treated fabric, treated fabric washed 20 times, and treated fabric washed 50 times. Each test subject served as their own control. Each fabric treatment was tested using an "arm-in-cage" style assay against *Aedes aegypti* and *Anopheles albimanus*. The methods provided indicate that the study was conducted per EPA Product Performance Guideline, OPPTS 810.3700; however, the detailed methods were not provided. Fabric was fastened tight to the test subject's arm, and arms were placed for 15 minutes into cages containing 225±25 female mosquitoes of a single species. Test cages were 20000 cm^3 and mosquito density was approximately 1 female mosquito per 100 cm^3 of cage volume. The order of testing the treatments was randomized. This study assessed the number of bites; however, the methods for confirming bites were not provided.

In addition to the arm-in-cage assay, permethrin residues were also assessed for each treatment using Gas Chromatography-Mass Spectrometry (GC-MS).

(3) **Results:** Mean percent bite protection provided by the treated ACU fabric against *Ae. aegypti* and *An. albimanus* was greater than 98% through 50 launderings. No data were provided regarding bite through rates in the untreated control fabric treatment. Permethrin residues as measured using GS-MS for unwashed treated fabrics were 0.125 mg/cm^2, after 20 launderings 0.086 mg/cm^2, and after 50 launderings 0.036 mg/cm^2.

(4) **Conclusion: Upgradable.** This study as submitted does not support any efficacy claims for EPA Reg. No. 83588-1. This study was only conducted with four subjects. Adequate sample sizes for these types of studies are typically in the range of 8-10 subjects, but should be justified using a power analysis. Statistical justification for sample size selection is missing. The Agency cannot consider this study as presented in this MRID because the study is missing details regarding methods and also raw data. The data presented are summary statistics; however, the Agency cannot assess the variability in the data. In addition, no data are presented from the control tests to assess control bite through. For this study to be considered to support efficacy of the product, raw data and all methodological details must be submitted. Also, because the study only evaluated efficacy using four subjects, MRID 48256101 could not be used by itself, but would have to be accompanied by additional acceptable data showing efficacy of EPA Reg. No. 83588-1 against mosquitoes.

(5) **Special Note:** This study was conducted after the Human Studies Rule went into effect (April 7, 2006). Should the registrant decide to submit the raw data and methodology as outlined above, this study will need to be reviewed by the Human Studies Review Board.

IV. EXECUTIVE DATA SUMMARY:

(A) The submitted data do not support efficacy claims against mosquitoes.

Efficacy claims against ants, ticks, chiggers, flies, and midges are not acceptable because data were not submitted to support efficacy against these pests.

V. LABEL RECOMMENDATIONS:

(1) All uses and pests should be removed from the label because they are not supported by data.

(2) The following marketing claims are acceptable: None

(3) The following marketing claims are unacceptable: All

(4) The following MRIDs should be removed from the data matrix, as they are classified as “unacceptable” to support the product: 47871301, 48256101, 47853601

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 482561-01. Perry, M. The Efficacy of NoFly Zone. August 31, 2010.

OCSPP Product Performance Guideline: 810.3300 Treatments to control pests of humans and pets

Product Name: No Fly Zone Fabric
EPA Reg. No. or File Symbol: N/A
Decision number: N/A
DP number: N/A

Prepared for
Registration Division (7505)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-282

Primary Reviewer:
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Date: 12/21/2015

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Signature: Angela M. Edmonds
Date: 12/21/2015

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.
Summitec Corp. for the U.S. Environmental Protection Agency under Contract No. EP-W-11-014

EFFICACY STUDY DATA EVALUATION RECORD (REREGISTRATION)

Primary Reviewer's Name/Title: Chris Peterson, Toxicologist

STUDY TYPE:		PRODUCT PERFORMANCE: OCSPP 810.3300 Treatments to control pests of humans and pets
MRID:		482561-01. Perry, M. The Efficacy of NoFly Zone. August 31, 2010.
TYPE OF DATA CALL IN:		PDCI
TESTING FACILITY:		Natick Soldier Research, Development and Engineering Center, 15 Kansas Street, Natick, MA 01760
STUDY DIRECTOR or INVESTIGATOR:		None
SUBMITTER:		Heather Bjornson, Registration Agent
STUDY COMPLETED:		11/06/2010
CONFIDENTIALITY CLAIMS:		None
GOOD LABORATORY PRACTICE STUDY?:		The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.
TEST DETAILS:		• ACTIVE INGREDIENT NAME: See test materials section • A.I. %: See test materials section • PC CODE: 109701 • CAS NO: Not provided • FORMULATION TYPE: Treated fabric
APPLICATION RATES:		• TEST PRODUCT APPLICATION RATE(S): See test materials section • TEST PRODUCT ACTIVE INGREDIENT APPLICATION RATE(S): See test methods section
PEST(s) TESTED:		Yellow fever mosquito, *Aedes aegypti* Malaria mosquito, *Anopheles albimanus*

Efficacy Study Data Evaluation Record - Reregistration

Title: The Efficacy of NoFly Zone

Purpose/Objective: Not stated

Materials and Methods

Test Material(s): No Fly Zone fabric (50% cotton, 50% nylon), with Permethrin incorporated into the fabric at 0.52% by weight washed 0, 20 and 50 times.

Gas chromatograph analyses determined the fabric contained the following Permethrin concentrations following the specified number of washings: 0 washings: 0.125 mg/square cm, 20 washings: 0.086 mg/square cm, 50 washings: 0.036 mg/square cm.

Test Location: Natick, MA

Positive Control/Reference Standard, if used: Not used

Species Tested:

- Common name and scientific name of each species. Yellow fever mosquito, *Aedes aegypti*; malaria mosquito, *Anopheles albimanus*
- Life stage as egg or nymph or larvae including stadia; or adult and sex and age. Adult females, 5 to 11 days post emergence
- Describe the insecticide susceptibility status of the test population. Not reported
- Describe the origin of field collected strains. Not reported
- If female adults are used - are they gravid? No
- Describe rearing techniques.

  4.4.6.6.3.3.2 Insect Rearing. Insects for these studies shall be reared under optimal conditions for larvae, as described in OPPTS 810.3700, section (d)(1)(iii).

Experiment description:

- List the treatments including the untreated control:

No Fly Zone fabric (50% cotton, 50% nylon), with Permethrin incorporated into the fabric at 0.52% by weight washed 0, 20 and 50 times.

Gas chromatograph analyses determined the fabric contained the following Permethrin concentrations following the specified number of washings: 0 washings: 0.125 mg/square cm, 20 washings: 0.086 mg/square cm, 50 washings: 0.036 mg/square cm.

4.4.6.6.3.6 Controls. For each test condition a control shall be conducted. The control shall consist of the same fabric without the insect protection treatment and be identical size to the test swatch (see 4.4.6.6.2). Controls will be cut in clean area and stored in separate plastic bags to avoid residual permethrin contamination. Laundered controls shall be laundered separately and to the identical number of times as the treated fabric. Controls shall be worn on the arm opposite the treated specimens.

- Include a description of:
  - Test arenas and/or apparatus (include site description and location):

4.4.6.6. Percent (%) Biting Protection Assay. Percent (%) bite protection shall be measured on finished permethrin treated garments, class 3 and class 4, under three test conditions and using a control specimen (non-permethrin treated, garment classes 1 and 2) against the two selected insect species specified in 4.4.6.6.3. the three test conditions shall be one unlaundered, two: after 20 launderings and three: after 50 launderings from garments produced in the same lot. Corresponding permethrin content for each of these conditions will be measured as specified in 4.4.6.5 to correlate biological toxicity with the particular garment treatment used to meet requirements specified in 3.3.10.

4.4.6.6.3.2 Fastening Test Specimen. Section (3)(iii) recommends "fastening a strip of the impregnated material to the test subject's forearm." This will be accomplished by utilizing specimen size specified in 4.4.6.6.2 (see Figure 15) and ensure it covers the entire forearm of the test subject without gaps for insect access. With the arm in the pronated position, the fastening seam that closes the specimen on the volunteer's arm shall be located on the top of the forearm. Attachment of the treated specimen will be done with gloved hand, which will be disposed of prior to attaching the control to alternate arm.

4.4.6.6.3.3.3 Cage Conditions. A cage density of 225 $\pm$25 female insects per cage is required to meet the biting pressure density of at least one female mosquito per 100 cm^3 cage volume. (Cages shall be 20,000 cm^3, with a sleeved opening for the arm of the volunteer to be inserted.) Cages shall be constructed of a lightweight clear plastic on 4 sides, with the side opposite the cloth sleeve containing a screen covered by a plastic flap. Tests shall be conducted with fluorescent lights on and under room conditions (22-27°C, and 40-80% RH). The temperature and RH during the test shall be recorded and reported.

4.4.6.6.3.5 Volunteer's Test Area. The test area shall consist of the region from the wrist to approximately ½ inch before the elbow. Fabric material shall be secured around the forearm to eliminate gaps between the arm and material and with the fastened seam positioned on the top of the forearm as specified in 4.4.6.6.3.2. The ends of the garment, near the wrist and elbow shall be sealed with protective tape of adequate thickness to prevent insects from biting through the tape. The hand shall be gloved with a glove of appropriate thickness to prevent biting through to the hand.

4.4.6.6.3.7 Biting Exposure. Arms containing the treated specimens shall be exposed to a cage of insects for 15 min. Since both arms shall contain fabric (one as the control, one as the treatment), the order of the exposure periods shall be randomized; however, effort should be made to run each period consecutively, with as little elapsed time as possible in between testing of a volunteer's arms.

  - Method(s) of application: Impregnated fabric

- Number of replicates per treatment: 3

4.4.6.6.1 Number of determinations. Three determinations will be run for each of the 2 insect species (see 4.4.6.6.3.3). Each determination for each insect is conducted with 4 volunteers using 3 different fabric conditions; unlaundered, 20 launderings and 50 launderings and compared to non-permethrin treated control. One set of controls will be used for the 3 determinations for each volunteer (see 4.4.6.6.3.6). The total number of specimens for the 3 determinations is outlined below. It is estimated that one blouse yields 6 specimens and one trouser yields 4 specimens consisting of largely a single ply fabric area (see 4.4.6.6.2).

- Number of individuals per replicate: 225 ± 25
- Length of exposure to treatment (time in seconds, minutes or hours): 15 min
- Were tested specimens transferred to clean containers?: NA, treated volunteer arm removed from cage
- Experimental conditions (state relative humidity, temperature, and photoperiod): containing a screen covered by a plastic flap. Tests shall be conducted with fluorescent lights on and under room conditions (22-27°C, and 40-80% RH). The temperature and RH during the test shall be recorded and reported.
- The type of harborage if used in the experiment: Not used, see test apparatus description above
- The data and/or endpoints that were recorded and how they were assessed (e.g., prodded with a needle to see if specimens move): Bite protection after 15 min exposure by using the following formula:

$$\% \text{ Bite Protection} = \frac{(B_{NC}/F_C) - (B_T/F_C)}{(B_{NC}/F_C)}$$

where:

B_{NC} = bites recorded on the arm covered by the negative control fabric

F_C = female insects in the cage that are capable of biting at the start of the 15-min period

BT = bites recorded on the arm that was covered by the treated fabric.

- Report if morbidity and mortality were recorded separately: NA
- Statistical analysis conducted and justification for selecting the approach to data analysis and statistics used (were data corrected to account for abnormalities in the data/study design, what level of significance was used, what were the confidence intervals around the mean value(s), was a median value also reported?): Not performed

Data Reported/Results

		Initial			20 Launderings			50 Launderings		
Sample Set	#	mg/cm²	%Bite Protection		mg/cm²	%Bite Protection		mg/cm²	%Bite Protection	
			Ae. Aeg.	An. Alb.		Ae. Aeg.	An. Alb.		Ae. Aeg.	An. Alb.
Burlington-ACU	1	0.126	98.8%	99.2%	0.087	100.0%	98.1%	0.035	100.0%	100.0%
	2	0.128	99.7%	97.7%	0.086	99.6%	99.0%	0.037	100.0%	100.0%
	3	0.122	99.3%	98.6%	0.084	100.0%	100.0%	0.037	100.0%	100.0%
	AVG.	**0.125**	**99.3%**	**98.5%**	**0.086**	**99.9%**	**99.0%**	**0.036**	**100.0%**	**100.0%**
	Total %Bite Avg.		**98.9%**			**99.5%**			**100.0%**	

- Deviations or amendments from the protocol. None reported
- For each tested species, report the % efficacy (e.g. knockdown, mortality, repellency) for each treatment group. Include the following information, if applicable:
    - Timepoints (e.g., 4 h, 24 h) at which greater than 90% efficacy was observed. 15 min against both species after 0, 20 and 50 washings
    - Tested a.i. application rate: 0 washings: 0.125 mg/square cm, 20 washings: 0.086 mg/square cm, 50 washings: 0.036 mg/square cm
    - Surface tested, for residual studies (e.g. ceramic tile, wood panel): Fabric
    - Formulation type (e.g. aerosol, granular): Treated fabric
    - Application type (e.g. direct, surface, area): Surface
    - Timepoints at which corresponding control mortality is greater than 10%. NA

- Permethrin incorporated into fabric caused ≥90% bite protection against yellow fever mosquito and malaria mosquito for 15 min exposure after 0, 20 and 50 washings.